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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,440	03/04/2002	Grant McFadden	MDSP-P01-002	3416

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,440

Applicant(s)

MCFADDEN ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 26-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/14/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I and species of binding to the complex in the reply filed on 01/03/2005 is acknowledged. The traversal is on the ground(s) that group I and III are closely related and share common features, and assay system in group I and II may overlap, therefore examination of all groups would not put a serious burden on the examiner. This argument has been fully considered but found unpersuasive because searching all three groups puts a serious burden on the examiner for the reasons set forth in the previous Office action. Each of the three different groups have different active steps using different apparatus and/or testing procedures that require separate searches in different US class and subclasses, and/or in non-patent literature. Groups II requires testing of efficacy and toxicity in vivo animals and group III requires using mass spectrometry, which the elected invention does not require. The requirement is still deemed proper and is therefore made FINAL.

Claims 26-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-37 are pending and claims 1-25 are examined to the extent they are drawn to the elected species.

Sequence Rules

The specification is objected because the application contains sequence disclosures at Fig. 4, 5, 11 but the corresponding SEQ ID NOs are not identified in the specification. If SEQ ID NO to each of the sequences at the fore-mentioned Fig. exists, then adding the corresponding SEQ ID NO in the Fig. legends would obviate this

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objection. If any of the numerous sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) does not have a SEQ ID NO, then this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. 37 CFR 1.821(a) presents a definition for "nucleotide and/or amino acid sequences." Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. "Specifically defined" means those amino acids other than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2 (see MPEP § 2422). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Objections

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

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required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 25 depends on claim 24 drawn to method involving a yeast two-hybrid assay or reverse yeast two-hybrid assay. US 20030044847 A1 (06 March 2003) at paragraph [0004] teaches that the limitation "Interaction Trap System" in claim 25 is synonymous with a yeast two-hybrid assay. This suggests that "reverse ITS" in claim 25 is also synonymous with a reverse yeast two-hybrid assay in claim 25. In other words, "Interaction Trap System" and "reverse ITS" are alias for a yeast two-hybrid assay and a reverse yeast two-hybrid assay, respectively, without any difference in the scope of the claimed property boundary.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: an step linking the active steps of A)-C) in the base claim 1 to the purpose set out in the preamble of the claimed invention. In other words, the claims as currently construed, especially claim 1 is missing a step how the agents are identified.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, and 10-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yin et al., (CN of IDS filed on 02/14/2005, 1994, Nature vol. 369, pages 321-3).

Claims 1-4, 8, and 10-22 are broadly interpreted as drawn to method of screening a potential anti- or pro-apoptotic agent that binds to BAX protein in a reaction mixture, wherein said agent is polypeptide (claim 2, and 3) or at least 10 polypeptides (claim 4), wherein the method involves further testing of the agent to see whether the agent possess the ability of possessing pro- or anti-apoptotic activity (claim 8) in a cell (claim 23), and wherein claim 10-22 are drawn to cell-free testing system (claims 10, 11, 20) of lysate, derived from mammalian cells (claim 22), wherein the lysate containing a recombinantly made protein (claim 21), with various degrees of protein purity (claim 12, and 13), and the protein or agent being used is immobilized on a solid support (claim 14, 16) and the immobilization is effected by an antibody (claim 15).

Yin et al., teach (at Figs. 3, and 4 and also from page 322, right column, 3rd paragraph to page 323) method of screening a potential anti- or pro-apoptotic agent (i.e. at least 10 different Bcl-2 mutants and the wild type Bcl-2) that binds to BAX protein in a reaction mixture in a cell-free testing system of lysate, derived from FL5.12 cells

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wherein the lysate containing a recombinantly made BAX protein with various degrees of protein purity, and the protein or agent being used is immobilized on a solid support (i.e. being transferred to nitrocellulose membrane), and the protein in nitrocellulose membrane is "effected... by indirect conjugation via an intermediate molecule" (note the claimed limitation in the instant claim 14) of an antibody.

As for further testing of the agent to see whether the agent possess the ability of possessing pro- or anti-apoptotic activity (instant claim 8), Yin et al., at Fig. 2 teach that method of testing the agent (the various Bcl-mutants and wild-type) to see whether the agent possess the ability of possessing pro- or anti-apoptotic activity.

Thus, Yin et al., anticipates claims 1-4, 8, and 10-22.

Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5622852 A (22 April 1997, the '852 patent from now on).

Claims 1-25 are broadly interpreted as drawn to method of screening a potential anti- or pro-apoptotic agent that binds to BAX protein in a reaction mixture, wherein said agent is polypeptide (claim 2, and 3) or at least 10 to 10,1000 polypeptides to (claims 4-7), wherein the method involves further testing of the agent to see whether the agent possess the ability of possessing pro- or anti-apoptotic activity (claim 8) in a cell (claim 23), and wherein claims 9, and 23-25 are drawn to testing involving in whole cell, more specially a yeast two hybrid system (ITS) in claims 24 and 25, and claim 10-22 are drawn to cell-free testing system (claims 10, 11, 20) of lysate, derived from mammalian cells (claim 22), wherein the lysate containing a recombinantly made protein (claim 21),

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with various degrees of protein purity (claim 12, and 13), and the protein or agent being used is immobilized on a solid support (claim 14, 16) by an antibody or biotin (claim 15).

The '852 patent (at Fig. 3a, 11, 15, columns 3, 4, 39-60) teach method of screening a potential anti- or pro-apoptotic agent that binds to BAX protein in a reaction mixture, wherein said agent is polypeptide or at least 10 to 10,1000 polypeptides, wherein the method involves further testing of the agent to see whether the agent possess the ability of possessing pro- or anti-apoptotic activity, in a cell and a testing system involving in whole cell, more specially a yeast two hybrid system (ITS) or reverse yeast two hybrid system in and cell-free testing system of lysate, derived from mammalian cells, wherein the lysate containing a recombinantly made protein, with various degrees of protein purity, and the protein or agent being used is immobilized on a solid support by an antibody or biotin.

Thus, The '852 patent anticipates claims 1-25.

Double Patenting

Claim 25 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 24. US 20030044847 A1 (06 March 2003) at paragraph [0004] teaches that the limitation "Interaction Trap System" in claim 25 is synonymous with a yeast two-hybrid assay. This suggests that "reverse ITS" in claim 25 is also synonymous with a reverse yeast two-hybrid assay in claim 25. In other words, "Interaction Trap System" and "reverse ITS" are alias for a yeast two-hybrid assay and a reverse yeast two-hybrid assay, respectfully, without any difference in the scope of the claimed property boundary. When two claims in an application are duplicates or else are so close in

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content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Judy Ladrangan for Art Unit 1642 whose telephone number is 571-272-0536.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
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A handwritten signature in cursive script, appearing to read "misook yu", with a long horizontal flourish extending to the right.